ADOPTED REGULATION OF

THE STATE BOARD OF PHARMACY

LCB File No. R128-10

Effective December 16, 2010

EXPLANATION – Matter in ***italics*** is new; matter in brackets **[**~~omitted material~~**]** is material to be omitted.

AUTHORITY: §§1, 3 and 4, NRS 639.070; §2, NRS 639.070, 639.071 and 639.072.

A REGULATION relating to pharmacy; establishing procedures concerning refrigerators and freezers used in pharmacies to store medicine; authorizing the prescription department of a pharmacy to have a freezer that is used to store medicine; prohibiting the storage of any food or beverage in certain freezers used to store medicine in the prescription department of a pharmacy; and providing other matters properly relating thereto.

Section 1. Chapter 639 of NAC is hereby amended by adding thereto a new section to read as follows:

1. The temperature in a refrigerator that is used to store medicine in the prescription department of a pharmacy must be maintained between 36 degrees Fahrenheit and 46 degrees Fahrenheit.

2. The temperature in:

(a) A freezer section of a refrigerator described in subsection 1 if the freezer section is used to store medicine must be maintained below 32 degrees Fahrenheit; and

(b) A freezer that is used to store medicine in the prescription department of a pharmacy must be maintained below 32 degrees Fahrenheit.

3. If the temperature in a refrigerator, freezer section of a refrigerator, or freezer is outside the range required by subsection 1 or 2, as applicable:

(a) The person who discovers that the temperature is outside the range, regardless of whether the discovery was made with the assistance of the alarm on a programmable device required pursuant to NAC 639.525, shall:

(1) Make a record documenting the temperature and, if applicable, the reading from the programmable device; and

(2) Inform the managing pharmacist of the temperature in the refrigerator, freezer section of the refrigerator, or freezer;

(b) The managing pharmacist shall ensure that action is taken to correct the temperature in the refrigerator, freezer section of the refrigerator, or freezer and, after verifying that such corrective action has been taken, shall initial the record made pursuant to paragraph (a); and

(c) A pharmacist shall inspect the contents of the refrigerator, freezer section of the refrigerator, or freezer, as applicable, to determine whether the contents of the refrigerator, freezer section of the refrigerator, or freezer are safe to keep or should be discarded. If the pharmacist determines that those contents must be discarded, the pharmacist shall ensure that the contents are discarded.

Sec. 2. NAC 639.469 is hereby amended to read as follows:

639.469 1. A pharmacy shall have adequate space necessary for the storage, compounding, labeling, dispensing, distribution and sterile preparation of drugs prepared in the pharmacy.

2. The pharmacy must be kept clean and arranged in an orderly manner. All required equipment must be clean and in good operating condition.

3. A sink with hot and cold running water must be available to all personnel of the pharmacy and must be maintained in a sanitary condition at all times.

4. The pharmacy must be well lighted and ventilated.

5. The temperature of the pharmacy must be maintained within a range compatible with the proper storage of drugs. The temperature of the refrigerator must be maintained within ~~[a range compatible with the proper storage of drugs requiring refrigeration.]~~ ***the range set forth in subsection 1 of section 1 of this regulation.***

6. The pharmacy must have a locked storage area for controlled substances listed in schedule II and other controlled substances requiring additional security.

7. Flammable materials must be stored in a designated area. The area must meet the requirements of local and state fire laws.

Sec. 3. NAC 639.525 is hereby amended to read as follows:

639.525 ***1.*** The prescription department in each licensed pharmacy must contain the following minimum work area and equipment for the compounding and dispensing of drugs:

~~[1.]~~ ***(a)*** A prescription counter on which to work, with a free working surface of not less than 3 feet in width and 2 feet in depth for each person who is compounding or dispensing drugs within the prescription department, including, without limitation, each registered pharmacist and pharmaceutical technician who is compounding or dispensing drugs within the prescription department. This working surface must be reserved for and restricted solely to the compounding and dispensing of drugs.

~~[2.]~~ ***(b)*** A free floor space behind the prescription counter that is not less than 8 feet in length and 4 feet in width.

~~[3.]~~ ***(c)*** A refrigerator that is equipped with ~~[a]~~ ***:***

(1) A thermometer to ensure proper control of temperature ~~[, a]~~ ***; and***

(2) A programmable device for monitoring temperature which includes an alarm that records when the temperature falls outside the range required by subsection 1 of section 1 of this regulation.

(d) A sink that is suitable for cleaning the required pharmaceutical equipment and is supplied with hot and cold running water, soap and detergent, and a clean and sanitary disposal container for wastes.

~~[4.]~~ ***(e)*** If the pharmacy compounds prescriptions that require the measurement of weight, scales and balances for medium and light weighing, at least one of which must be sensitive to 1/2 grain, with weights, including, without limitation, apothecary and avoirdupois, from 1/2 grain to 4 ounces and from 0.02 gm to 100 gm.

~~[5. If the pharmacy prepares sterile products, a laminar airflow hood that is certified at least annually.~~

~~6.]~~ ***(f)*** Capsule and tablet counters and other devices and equipment necessary to compound and dispense drugs.

~~[7.]~~ ***(g)*** A facsimile machine that:

~~[(a)]~~ ***(1)*** Uses paper of such quality; and

~~[(b)]~~ ***(2)*** Prints in such a manner,

➥ that documents printed by the machine are usable and readable for at least 2 years. As used in this ~~[subsection,]~~ ***paragraph,*** "facsimile machine" includes, without limitation, a computer that has a facsimile modem through which documents can be sent and received.

2. In addition to the requirements of subsection 1, the prescription department in a licensed pharmacy may contain a freezer that is used to store medicine. If the prescription department in a licensed pharmacy contains such a freezer, the freezer must be equipped with

a programmable device for monitoring temperature which includes an alarm that records when the temperature falls outside the range required by subsection 2 of section 1 of this regulation.

Sec. 4. NAC 639.528 is hereby amended to read as follows:

639.528 1. Food for consumption by the public must not be prepared in the prescription department of a pharmacy.

2. A pharmacist or a member of the staff of a pharmacy may prepare food in the prescription department of the pharmacy if the food is for his or her own personal consumption.

3. No food or beverage may be stored in ~~[a]~~ ***:***

(a) A refrigerator that is used to store medicine in the prescription department of a pharmacy ~~[.]~~ ***;***

(b) The freezer section of such a refrigerator if the freezer section is used to store medicine; or

(c) A freezer that is used to store medicine in the prescription department of a pharmacy.

INFORMATIONAL STATEMENT

The informational statement required by NRS 233B.066 numerically conforms to the subsections of the statute as follows:

1. A DESCRIPTION OF HOW PUBLIC COMMENT WAS SOLICITED, A SUMMARY OF PUBLIC RESPONSE, AND AN EXPLANATION HOW OTHER INTERESTED PERSONS MAY OBTAIN A COPY OF THE SUMMARY.

Public comment was solicited through public notices posted in county courthouses and through mailings to interested parties.

There was no public response expressed relative to this proposed regulation.

2. THE NUMBER OF PERSONS WHO: (A) ATTENDED EACH HEARING; (B) TESTIFIED AT EACH HEARING; AND (C) SUBMITTED TO THE AGENCY WRITTEN STATEMENTS.

The number of persons who attended the hearing was __12___.
The number of persons who testified at the hearing was __1___.
The number of agency submitted statements was __0___.

3. A DESCRIPTION OF HOW COMMENT WAS SOLICITED FROM AFFECTED BUSINESSES, A SUMMARY OF THEIR RESPONSE, AND AN EXPLANATION HOW OTHER INTERESTED PERSONS MAY OBTAIN A COPY OF THE SUMMARY.

Comments were solicited from affected businesses through posting of public notices in the county courthouses, by direct mailings to all interested persons who have requested notices of board of pharmacy meeting agendas and by direct mailings to professional and trade associations.

There was no response from affected businesses relative to this proposed regulation.

4. IF THE REGULATION WAS ADOPTED WITHOUT CHANGING ANY PART OF THE PROPOSED REGULATION, A SUMMARY OF THE REASONS FOR ADOPTING THE REGULATION WITHOUT CHANGE.

The proposed regulation was adopted with minor changes.

5. THE ESTIMATED ECONOMIC EFFECT OF THE REGULATION ON THE BUSINESS WHICH IT IS TO REGULATE AND ON THE PUBLIC. THESE MUST BE STATED SEPARATELY, AND IN EACH CASE MUST INCLUDE:

A) BOTH ADVERSE AND BENEFICIAL EFFECTS.

This regulation should have minor economic impact on affected businesses and no economic impact on the public.

B) BOTH IMMEDIATE AND LONG-TERM EFFECTS.

This regulation should have only a minor economic impact on affected businesses and should have no economic impact on the public.

6. THE ESTIMATED COST TO THE AGENCY FOR ENFORCEMENT OF THE PROPOSED REGULATION.

Enforcement of the regulation will be performed during annual inspections of all pharmacies. There will be no additional cost incurred by the board.

7. A DESCRIPTION OF ANY REGULATIONS OF OTHER STATE OR GOVERNMENT AGENCIES WHICH THE PROPOSED REGULATION OVERLAPS OR DUPLICATES AND A STATEMENT EXPLAINING WHY THE DUPLICATION OR OVERLAPPING IS NECESSARY. IF THE REGULATION OVERLAPS OR DUPLICATES A FEDERAL REGULATION, THE NAME OF THE REGULATING FEDERAL AGENCY.

The Board of Pharmacy is not aware of any similar regulations of other state or government agencies that the proposed regulation overlaps or duplicates.

8. IF THE REGULATION INCLUDES PROVISIONS WHICH ARE MORE STRINGENT THAN A FEDERAL REGULATION WHICH REGULATES THE SAME ACTIVITY, A SUMMARY OF SUCH PROVISIONS.

The Board of Pharmacy is not aware of any similar regulations of the same activity in which the federal regulation is more stringent.

9. IF THE REGULATION PROVIDES A NEW FEE OR INCREASES AN EXISTING FEE, THE TOTAL ANNUAL AMOUNT THE AGENCY EXPECTS TO COLLECT AND THE MANNER IN WHICH THE MONEY WILL BE USED.

This regulation does not provide a new or increase of fees.